

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
6 May 2004 (06.05.2004)

PCT

(10) International Publication Number
WO 2004/037228 A1

- (51) International Patent Classification⁷: **A61K 9/20**,
9/28, 9/16, 31/517
- (21) International Application Number:
PCT/IB2003/004677
- (22) International Filing Date: 22 October 2003 (22.10.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
1023/DEL/2002 22 October 2002 (22.10.2002) IN
- (71) Applicant (for all designated States except US): **RAN-
BAXY LABORATORIES LIMITED** [IN/IN]; 19, Nehru
Place, 110019 New Delhi, Delhi (IN).
- (72) Inventors; and
(75) Inventors/Applicants (for US only): **VISWANATHAN,**
Narayanan, Badri [IN/IN]; Plot No. 25, 2nd Main Road,
Kannan Nagar, 500091 Madipakkam, Chennai (IN). **RA-
MAKRISHNAN, Sankar** [IN/IN]; 24, River Bank Street,
Madukkur, 614903 Thanjavur District, Tamil Nadu (IN).
RAGHUVANSHI, Rajeev, Singh [IN/IN]; D-8/8131,
- (81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE,
GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR,
KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK,
MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT,
RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR,
TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,
SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM,
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report
- For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: SUSTAINED RELEASE COMPOSITIONS CONTAINING ALFUZOSIN

(57) Abstract: The present invention relates to pharmaceutical compositions of alfuzosin or pharmaceutically acceptable salt, solvate, enantiomers or mixtures thereof, that release the active ingredient over an extended period of time. The pharmaceutical composition can be a sustained release oral dosage form that includes a single functional layer and, optionally, one or more nonfunctional layers adjacent to the single functional layer. The single functional layer includes alfuzosin or pharmaceutically acceptable salt, solvate, enantiomers or mixtures thereof and one or more release retarding ingredients.

WO 2004/037228 A1

INTERNATIONAL SEARCH REPORT

PCT 03/04677

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/20 A61K9/28 A61K9/16 A61K31/517

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, MEDLINE, EMBASE, BIOSIS, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 820 319 A (ELLIPSE PHARMACEUTICALS) 9 August 2002 (2002-08-09) page 3, line 4 -page 4, line 5 examples 1,5 claims 1,10	1-40
X	US 5 589 190 A (ANDRIEU VERONIQUE ET AL) 31 December 1996 (1996-12-31) cited in the application column 1, line 23 - line 54 examples 1-3 claim 1	1-40

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

9 February 2004

Date of mailing of the international search report

17/02/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Hedegaard, A

BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT

PC 03/04677

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94 27582 A (DANBIOSYST UK ; ILLUM LISBETH (GB); WATTS PETER (GB); FARRAJ NIDAL) 8 December 1994 (1994-12-08) cited in the application page 3, line 11 -page 4, line 17 example 1	1-40
X	US 6 149 940 A (JARREAU FRANCOIS XAVIER ET AL) 21 November 2000 (2000-11-21) cited in the application example 1 claim 1	1-40
X	EP 1 064 938 A (SANOFI SYNTHELABO) 3 January 2001 (2001-01-03) example 2 claims 1,7-12	1-40

BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT

PC 03/04677

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
FR 2820319	A	09-08-2002	FR 2820318 A1	09-08-2002
			FR 2820319 A1	09-08-2002
			CA 2437630 A1	15-08-2002
			EP 1368002 A2	10-12-2003
			WO 02062321 A2	15-08-2002
US 5589190	A	31-12-1996	FR 2717388 A1	22-09-1995
			AT 203672 T	15-08-2001
			AU 681236 B2	21-08-1997
			AU 1495595 A	28-09-1995
			CA 2144917 A1	22-09-1995
			CN 1116524 A	14-02-1996
			CZ 9500704 A3	18-10-1995
			DE 69521924 D1	06-09-2001
			DE 69521924 T2	11-04-2002
			EP 0673650 A1	27-09-1995
			FI 951300 A	22-09-1995
			HU 72635 A2	28-05-1996
			IL 113053 A	22-12-1999
			JP 7258085 A	09-10-1995
			NO 951055 A	22-09-1995
			NZ 270748 A	21-12-1995
			PL 307773 A1	02-10-1995
			SK 36595 A3	08-11-1995
			ZA 9502290 A	24-01-1996
WO 9427582	A	08-12-1994	AT 171370 T	15-10-1998
			AU 684786 B2	08-01-1998
			AU 6802094 A	20-12-1994
			CA 2163340 A1	08-12-1994
			DE 69413534 D1	29-10-1998
			DE 69413534 T2	18-03-1999
			DK 700285 T3	15-02-1999
			EP 0700285 A1	13-03-1996
			ES 2124889 T3	16-02-1999
			FI 955730 A	26-01-1996
			WO 9427582 A1	08-12-1994
			GB 2292315 A ,B	21-02-1996
			JP 9504779 T	13-05-1997
			NO 954583 A	14-11-1995
US 6149940	A	21-11-2000	FR 2752737 A1	06-03-1998
			AT 200864 T	15-05-2001
			AU 724490 B2	21-09-2000
			AU 4020197 A	19-03-1998
			BG 63768 B1	29-12-2002
			BG 103138 A	30-09-1999
			BR 9713237 A	04-04-2000
			CA 2264250 A1	05-03-1998
			CN 1228700 A	15-09-1999
			CY 2284 A	04-07-2003
			CZ 9900655 A3	16-06-1999
			DE 69704712 D1	07-06-2001
			DE 69704712 T2	29-11-2001
			DK 938318 T3	20-08-2001
			EE 9900090 A	15-10-1999
			EP 0938318 A1	01-09-1999
			ES 2159400 T3	01-10-2001

BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT

PC 03/04677

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6149940	A	WO 9808515 A1	05-03-1998
		GR 3036291 T3	31-10-2001
		HK 1020875 A1	23-11-2001
		IL 128146 A	11-01-2001
		JP 2000514462 T	31-10-2000
		KR 2000035929 A	26-06-2000
		NO 990944 A	27-04-1999
		NZ 334018 A	29-06-1999
		PL 331862 A1	16-08-1999
		PT 938318 T	30-10-2001
		RU 2183459 C2	20-06-2002
		SI 938318 T1	31-12-2001
		SK 27099 A3	10-12-1999
		TR 9900289 T2	21-12-2000
		TW 522023 B	01-03-2003
		ZA 9707766 A	23-02-1998
EP 1064938	A 03-01-2001	EP 1064938 A1	03-01-2001
		AU 6274700 A	31-01-2001
		BR 0011999 A	05-03-2002
		CA 2370067 A1	04-01-2001
		CN 1358088 T	10-07-2002
		CZ 20014639 A3	17-04-2002
		WO 0100182 A1	04-01-2001
		EP 1194131 A1	10-04-2002
		HU 0202259 A2	28-12-2002
		JP 2003503341 T	28-01-2003
		NO 20016282 A	27-02-2002
		SK 19102001 A3	09-05-2002
		TR 200103604 T2	22-04-2002
		ZA 200109849 A	29-11-2002

BEST AVAILABLE COPY